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(71) Applicants (for all designated States except US):  
**PHAROMED A/S** [DK/DK]; Skovbrynet 57, DK-2880  
Bagsvaerd (DK). **COLOPLAST A/S** [DK/DK]; Høltedam  
1, DK-3050 Humlebaek (DK).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **KIKRBY, Nikolai**,  
Søren [DK/DK]; Læssøesgade 14, 1.sal, DK-2200 Copen-  
hagen N (DK). **SAMUELSEN, Peter, Borman** [DK/DK];  
Bukkeballevvej 18, DK-2960 Rungsted Kyst (DK).

(74) Agent: **ZACCO DENMARK A/S**; Hans Bekkevolds Allé  
7, DK-2900 Hellerup (DK).

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For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: COMPOSITION FOR VACCINATION

(57) Abstract: The present invention provides novel compositions for transdermal delivery of at least one immunogen to an individ-  
ual, which compositions comprise (a) said at least one immunogen (b) an occlusion vehicle and (c) an immunogen delivery system  
in the form of a PosIntro or a cationic ISCOM or comprising at least one saponin and at as well as a process for preparation of the  
compositions. The invention further provides constructs comprising these compositions. The compositions and constructs may be  
used in methods for generating an immunological response, methods for treating or preventing a condition of illness and methods  
for vaccination. The occlusion vehicle is e.g. a pressure sensitive adhesive, such as a hydrocolloid adhesive or a hydrogel adhesive,  
which may be cross-linked, or the occlusion vehicle may be non-adherent.



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## INTERNATIONAL SEARCH REPORT

Internatio; pplication No

PCT/ 03/00654

A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61K39/39 A61L15/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, CHEM ABS Data, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02 074325 A (ADAMS CHRISTOPHER L ;MIRANDA JESUS (US); GLENN GREGORY M (US); HAM) 26 September 2002 (2002-09-26)	1-39
X	the whole document	40
Y	WO 99 11247 A (FOLDVARI MARIANNA ;BACA ESTRADA MARIA (CA); PHARMADERM LAB LTD (CA) 11 March 1999 (1999-03-11)	1-39
X	the whole document	40
Y	WO 00 07621 A (SMITHKLINE BEECHAM BIOLOG ;FRIEDE MARTIN (BE); GARCON NATHALIE (BE) 17 February 2000 (2000-02-17)	1-39
Y	WO 92 21331 A (KABI PHARMACIA AB) 10 December 1992 (1992-12-10)	1-39
	the whole document	
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

10 February 2004

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

VIVECA NORÉN /EÖ

## INTERNATIONAL SEARCH REPORT

International Application No  
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category <sup>o</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 56420 A (CSL LTD ;COX JOHN COOPER (AU); RONNBERG BENGT JOHN LENNART (SE); S) 17 December 1998 (1998-12-17) the whole document ---	1-39
Y	WO 92 06710 A (NEDERLANDEN STAAT) 30 April 1992 (1992-04-30) the whole document ---	1-39
Y	WO 98 36772 A (CSL LTD ;MALLIAROS JIM (AU); MACFARLAN RODERICK IAN (AU)) 27 August 1998 (1998-08-27) the whole document ---	1-39
P,Y	WO 02 080981 A (KIRKBY NIKOLAI SOEREN ;PHAROMED AS (DK); DALSGAARD KRISTIAN (DK)) 17 October 2002 (2002-10-17) the whole document -----	1-39

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/DK 03/00654

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 37-39  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 37-39

Claims 37-39 relate to methods of treatment of the human or animal body by surgery or by therapy or diagnostic methods practised on the human or animal body (PCT Rule 39.1(iv)). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compounds or compositions.

## INTERNATIONAL SEARCH REPORT

Information on patent family members

Internatid

Application No

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03/00654

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 02074325	A	26-09-2002	EP 1381381 A1 WO 02074325 A1	21-01-2004 26-09-2002
WO 9911247	A	11-03-1999	AU 735955 B2 AU 8968498 A CA 2302494 A1 WO 9911247 A1 CN 1277551 T EP 1023054 A1 JP 2001514212 T NZ 503568 A US 5993852 A	19-07-2001 22-03-1999 11-03-1999 11-03-1999 20-12-2000 02-08-2000 11-09-2001 30-03-2001 30-11-1999
WO 0007621	A	17-02-2000	AU 738965 B2 AU 5509999 A CA 2339486 A1 WO 0007621 A2 EP 1102600 A2 JP 2002522397 T US 6506386 B1	04-10-2001 28-02-2000 17-02-2000 17-02-2000 30-05-2001 23-07-2002 14-01-2003
WO 9221331	A	10-12-1992	SE 502569 C2 AT 152620 T AU 680807 B2 AU 1925192 A CA 2103447 A1 DE 69219600 D1 DE 69219600 T2 EP 0587659 A1 ES 2103946 T3 FI 935314 A JP 7500084 T KR 227302 B1 NO 934315 A SE 9101665 A WO 9221331 A1 US 5603958 A	13-11-1995 15-05-1997 14-08-1997 08-01-1993 01-12-1992 12-06-1997 02-10-1997 23-03-1994 01-10-1997 29-11-1993 05-01-1995 01-11-1999 26-01-1994 01-12-1992 10-12-1992 18-02-1997
WO 9856420	A	17-12-1998	AU 725342 B2 AU 8003598 A WO 9856420 A1 EP 1019087 A1 JP 2002504101 T NZ 501641 A ZA 9805140 A	12-10-2000 30-12-1998 17-12-1998 19-07-2000 05-02-2002 22-12-2000 07-01-1999
WO 9206710	A	30-04-1992	NL 9002314 A AT 127024 T CA 2094600 A1 DE 69112634 D1 DE 69112634 T2 DK 555276 T3 EP 0555276 A1 ES 2075964 T3 GR 3017778 T3 WO 9206710 A1 US 5620690 A	18-05-1992 15-09-1995 24-04-1992 05-10-1995 08-02-1996 18-09-1995 18-08-1993 16-10-1995 31-01-1996 30-04-1992 15-04-1997

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International

Application No

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9836772	A	27-08-1998	AU 720855 B2	15-06-2000
			AU 5848898 A	09-09-1998
			WO 9836772 A1	27-08-1998
			EP 0986399 A1	22-03-2000
			JP 2001512464 T	21-08-2001
			NZ 336792 A	28-01-2000
			US 2002081329 A1	27-06-2002
			ZA 9801281 A	19-11-1998
<hr/>				
WO 02080981	A	17-10-2002	WO 02080981 A2	17-10-2002
			EP 1377320 A2	07-01-2004
			US 2003118635 A1	26-06-2003
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